CLAIMS

I claim:

1. A pharmaceutical composition for treating osteoporosis comprising at least one zwitterionic phospholipid and at least one bisphosphonate.

2. The composition of claim 1, wherein the zwitterionic phospholipid is present in an amount sufficient to reduce GI toxicity of the bisphosphonate and the bisphosphonate is present in an amount sufficient to reduce bone resorption.

3. The composition of claim 1, wherein the zwitterionic phospholipid is present in an amount sufficient to reduce GI toxicity of the bisphosphonate and improve bisphosphonate bio-availability when the composition is taken with food and the bisphosphonate is present in an amount sufficient to reduce bone resorption, increase in bone density and/or reduce bone fractures.

4. The composition of claim 3, wherein the amount of bisphosphonate is between about 0.1 mg per dose and about 1000 mg per dose and a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:0.1 and about 1:100.

5. The composition of claim 3, wherein the amount of bisphosphonate is between about 1 mg per dose and about 500 mg per dose and a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:0.5 and about 1:50.

6. The composition of claim 3, wherein the amount of bisphosphonate is between about 2 mg per dose and about 50 mg per dose and a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:1 and about 1:10.

7. The composition of claim 3, wherein the amount of bisphosphonate is between about 2 mg per dose and about 20 mg per dose and a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:1 and about 1:5.

8. The composition of claim 1, wherein the zwitterionic phospholipid is present in an amount sufficient to reduce GI toxicity of the bisphosphonate and the bisphosphonate is present in an amount sufficient to reduce bone resorption, increase in bone density and/or reduce bone fractures.

9. The composition of claim 8, wherein the bisphosphonate is present in an amount between about 0.1 mg per dose and about 1000 mg per dose and a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:0.1 and about 1:100.

10. The composition of claim 8, wherein the bisphosphonate is present in an amount between about 1 mg per dose and about 500 mg per dose and a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:0.5 and about 1:50.

11. The composition of claim 8, wherein the bisphosphonate is present in an amount between about 2 mg per dose and about 50 mg per dose and a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:1 and about 1:10.

12. The composition of claim 8, wherein the bisphosphonate is present in an amount between about 2 mg per dose and about 20 mg per dose and a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:1 and about 1:5.

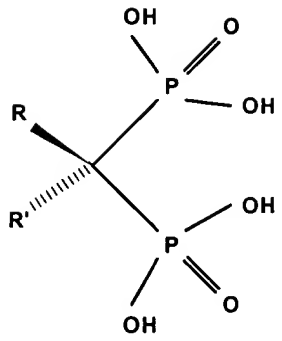
13. The composition of claim 1, wherein the zwitterionic phospholipid increases the bio-availability of the bisphosphonate from about 2 to about 20 fold.

14. The composition of claim 1, wherein the bisphosphonate is in its zwitterionic form and forms an ionic association complex with the zwitterionic phospholipid.

15. The composition of claim 1, further comprising a colloidal metal, a metal complex or a mixture or combination thereof.

16. The composition of claim 1, wherein the bisphosphonate is characterized by the general formula (I):

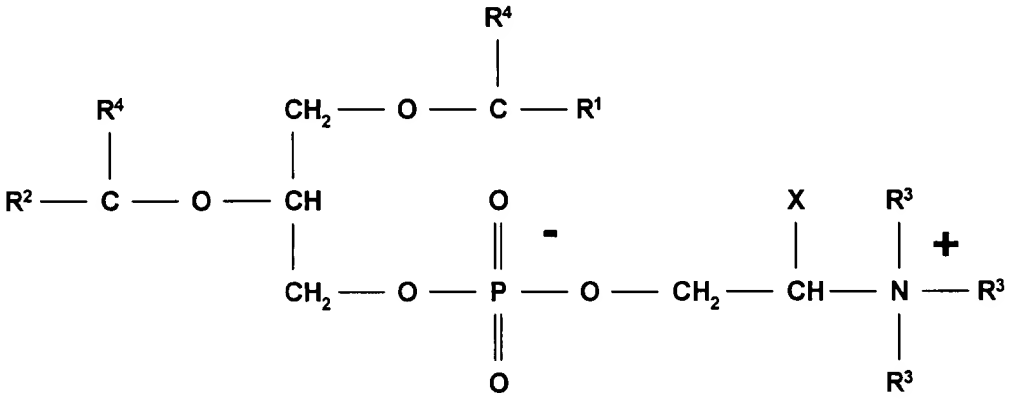
(I)



where R' is H, OH or Cl and R is: (a) an alkyl group having 1 to 6 carbon atoms, optionally substituted with amino, alkylamino. dialkylamino or heterocyclyl, where the alkyl groups in alkylamino and dialkylamino substituents have 1 to 5 carbon atoms and are the same or different in the case of the dialkylamino substituted alkyl groups; (b) a halogen; (c) an arylthio, preferably chlorosubstituted; (d) a cycloalkylamino having 5 to 7 carbon atoms; or (e) a saturated five or six membered nitrogen containing heterocyclyl having 1 or 2 heteroatoms.

17. The composition of claim 1, wherein the phospholipid is characterized by the of general formula (II):

(II)



where R_1 and R_2 are saturated or unsaturated substitutions ranging from 8 to 32 carbon atoms; R_3 is H or CH_3, and X is H or COOH; and R_4 is =O or H_2.

18. The composition of claim 1, wherein the bisphosphonate is selected from the group consisting of 3-amino-1-hydroxypropylidene-1,1-bisphosphonic acid (pamidronate), 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid (alendronate), N,N-dimethyl-3-amino-1-

hydroxypropylidene-1,1-bisphosphonic acid (mildronate, olpadronate), I-hydroxy-3- (N-methyl-N-pentylamino) propylidene-1,(N-methyl-N-pentylamino) propylidene-1, 1-bisphosphonic acid (ibandronate), I-hydroxy-2-(3-pyridyl) ethylidene-1,(3-pyridyl) ethylidene-1, 1-bisphosphonic acid (risedronate), 1-hydroxyethylidene-1,1-bisphosphonic acid (etidronate), 1-hydroxy-3- (l-pyrrolidinyl) propylidene-1,1-bisphosphonic acid, l-hydroxy-2- (1-imidazolyl) etylidene-l, 1-bisphosphonic(1-imidazolyl) etylidene-l, 1-bisphosphonic acid (zoledronate), 1-hydroxy-2-(imidazo [1,2-a] pyridin-3-yl) ethylidene-1,1-bisphosphonic acid (minodronate), 1- (4-chlorophenylthio) methylidene-l, 1-bisphosphonic acid (tiludronate), 1- (cycloheptylamino) methylidene-1,1-bisphosphonic acid (cimadronate, incadronate), 6-amino-1-hydroxyhexylidene-1,1-bisphosphonic acid (neridronate) and pharmaceutically acceptable salts thereof and mixtures and combinations thereof.

19. The composition of claim 1, wherein the bisphosphonate is selected from the group consisting of risedronate, alendronate, pamidronate and their pharmaceutically acceptable salts and mixtures and combinations thereof.

20. The composition of claim 1, wherein the zwitterionic phospholipid is selected from the group consisting of phosphatidyl cholines, phosphatidyl ethanolamines, phosphatidylinositol, phosphatidyl serines sphingomyelin or other ceramides, phospholipid containing oils, and mixtures and combination thereof.

21. The composition of claim 1, wherein the zwitterionic phospholipid is selected from the group consisting of phosphatidyl choline (PC), dipalmitoylphosphatidylcholine (DPPC), other disaturated phosphatidyl cholines, lecithin oils and mixture and combinations thereof.

22. A pharmaceutical composition, for treating osteoporosis, comprising a pharmaceutically effective amount of a bisphosphonate to reduce bone resorption and a sufficient amount of a zwitterionic phospholipid to reduce GI toxicity and increase the bio-availability of the bisphosphonate.

23. The composition of claim 22, the effective amount of the bisphosphonate comprises between

about 0.1 mg per dose and about 1000 mg per dose and the sufficient amount of zwitterionic phospholipid is such that a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:0.1 and about 1:100.

24. The composition of claim 22, further comprising a colloidal metal, a metal complex or mixtures or combinations thereof.

25. A pharmaceutical composition comprising a carrier, a pharmaceutically effective amount of a bisphosphonate to reduce bone resorption and a sufficient amount of a zwitterionic phospholipid to reduce GI toxicity and increase the bio-availability of the bisphosphonate.

26. The composition of claim 25, wherein effective amount of the bisphosphonate is between about 0.1 mg per dose and about 1000 mg per dose and the sufficient amount of zwitterionic phospholipid is such that a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:0.1 and about 1:100.

27. The composition of claim 25, further comprising a colloidal metal, a metal complex or mixtures or combinations thereof.

28. The composition of claim 25, wherein the medication is to be taken orally.

29. The medication of claim 25, wherein the medication is to be taken orally with food.

30. An oral medication for treating osteoporosis comprising an solid object comprising an inert carrier, a pharmaceutically effective amount a bisphosphonate to reduce bone resorption and an amount of a zwitterionic phospholipid sufficient to reduce GI toxicity and increase the bio-availability of the bisphosphonate.

31. The medication of claim 30, wherein the effective amount of the bisphosphonate is between about 0.1 mg per dose and about 1000 mg per dose and the sufficient amount of zwitterionic phospholipid is such that a ratio of bisphosphonate to zwitterionic phospholipid is between about

1:0.1 and about 1:100.

32. The medication of claim 30, further comprising a colloidal metal, a metal complex or a mixture or combination thereof.

33. A method for treating osteoporosis comprising the step of administering a composition comprising a pharmaceutically effective amount a bisphosphonate and an amount of a zwitterionic phospholipid sufficient to reduce GI toxicity and increase the bio-availability of the bisphosphonate.

34. The method of claim 33, wherein the effective amount of the bisphosphonate is between about 0.1 mg per dose and about 1000 mg per dose and the sufficient amount of zwitterionic phospholipid is such that a ratio of bisphosphonate to zwitterionic phospholipid is between about 1:0.1 to about 1:10.

35. The method of claim 33, further comprising a colloidal metal, a metal complex or mixtures or combinations thereof.

36. A method for making a bisphosphonate medicinal composition with reduced GI toxicity including the step of contacting a zwitterionic phospholipid and a bisphosphonate, where the composition has reduced GI toxicity and improved bio-availability of the bisphosphonate and causes a reduction in bone resorption.

37. The method of claim 36, wherein the contacting is under conditions where the phospholipid and the bisphosphonate are in their zwitterionic forms.

38. The method of claim 36, wherein the conditions are sufficient to promote the formation form ionic association complexes between the zwitterionic phospholipid and the zwitterionic bisphosphonate.

39. The method of claim 36, further comprising the step of admixing the composition with an inert carrier.

40. The method of claim 36, further comprising the step of mixing the composition for a time and at a temperature sufficient to promote intermolecular interaction between the zwitterionic phospholipid and the bisphosphonate.

41. The method of claim 40, wherein the mixing is sonicating and the time is between about 1 minute and 1 hour and the temperate is above the highest transition temperature (T_m) of the phospholipid in the composition.

42. The method of claim 36, wherein the contacting is in the presence of a metal complex, metal colloidal, or mixture or combination thereof.

43. A method for making a bisphosphonate medicinal composition with reduced GI toxicity including the steps of:

dissolving a zwitterionic phospholipid in an organic solvent;

removing the solvent to form a thin film of the zwitterionic phospholipid;

contacting the zwitterionic phospholipid film with a solution comprising a bisphosphonate, where the solution has low ionic strength and a pH sufficient to maintain the bisphosphonate and the phospholipid in their zwitterionic forms to form the composition; and

mixing the composition for a time and at a temperature sufficient to promote intermolecular interaction between the zwitterionic phospholipid and the bisphosphonate,

where the composition has reduced GI toxicity and improved bio-availability of the bisphosphonate and causes a reduction in bone resorption.

44. The method of claim 43, wherein the time is between about 1 minute and 1 hour and the temperate is above the highest transition temperature (T_m) of the phospholipid in the composition.

45. The method of claim 43, wherein the solution further comprises a metal complex, metal colloidal, or mixtures or combinations thereof.